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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,276	03/31/2004	Marc D. Better	14923US02	1162
<div>7590 05/04/2007 Janet M. McNicholas, Ph.D. McAndrews, Held & Malloy, Ltd. 34th Floor 500 West Madison Chicago, IL 60661</div>			<div>EXAMINER HADDAD, MAHER M</div>	
			<div>ART UNIT 1644</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 05/04/2007</div>	<div>DELIVERY MODE PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/816,276

Applicant(s)

BETTER ET AL.

Examiner

Maher M. Haddad

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2007 and 12 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32,34,35,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) 1-30,37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,32,34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 3/1/07 and 3/12/07, is acknowledged.
2. Claims 1-32, 34-35 and 37-38 are pending.
3. Claims 1-30 and 37-38 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.
4. Claims 31, 32, 34 and 35 are under examination as they read on a method for treating a mammal suffering from an EP-CAM mediated disease, disorder or condition comprising administering the human engineered anti-EP-CAM antibody and SEQ ID NO: 21, 19, 6, 8, 35, 37, 39, 41, 43 and 45.
5. In view of the amendment filed on 3/1/07 and 3/12/07, only the following rejections are remained.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e1) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

35 U.S.C. § 102(e), as revised by the AIPA and H.R. 2215, applies to all qualifying references, except when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. For such patents, the prior art date is determined under 35 U.S.C. § 102(e) as it existed prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

7. Claim 31-32 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ammons et al(2001), as is evidence by the specification on ¶6, 17 and 74 for the same reasons set forth in the previous Office Action mailed 9/11/06.

Applicant's arguments, filed 3/1/07 and 3/12/07, have been fully considered, but have not been found convincing.

Applicant submits that the subject matter as claimed, is not disclosed in the cited reference. Applicants submit that, according to MPEP 2133.03(a) II, mere knowledge of the invention by

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the public does not warrant rejection under 102(b), 102(b) bars public use or sale, not public knowledge. Ammons is not a public use nor is it a public sale and Applicants submit that the invention as claimed was not publicly disclosed. Specifically, Applicants submit that no sequence information is inherent in the disclosure of the generalized name of a molecule such as, ING-1 (heMAb).

Contrary to Applicant submission Ammons et al teachings constitute public use not public knowledge of the claimed antibodies (heMAb) in treating adenocarcinomas. The disclosure of the sequences is only further characterization of otherwise known product.

8. Claim 31-32 stand rejected under 35 U.S.C. 102(a) as being anticipated by XOMA A Leader in Therapeutic Antibodies, May 2002, as is evidence by the specification on ¶6, 17 and 74 for the same reasons set forth in the previous Office Action mailed 9/11/06.

9. Claim 31-32 stand rejected under 35 U.S.C. 102(a) as being anticipated by Better et al, May 2002, as is evidence by the specification on ¶6, 17 and 74 for the same reasons set forth in the previous Office Action mailed 9/11/06.

Applicant's arguments, filed 3/1/07 and 3/12/07, have been fully considered, but have not been found convincing.

Applicants submit that the claimed invention was not publicly disclosed. Specifically, Applicants submit that no sequence information is inherent in the disclosure of the generalized name of a molecule such as, ING-I(heMAb). Moreover, the work described in the cited publications was carried out by the inventors of the claims in the present application and therefore the work was not known by others or described in a printed publication before the invention by the present applicants, as would be required to support a rejection under 35 U.S.C. § 102(a).

However, it is the Examiner position that the disclosure of the sequences is further characterization of otherwise old product. Further, the Examiner notes that the current application has only two inventors while the Better et al reference 12 authors, thus qualifies as "by others". As for XOMA reference, the work described in the reference does not point to Applicants as argued. Therefore, it is qualify "by others", in the absence of evidence to the contrary.

10. Claim 31-32 stand rejected under 35 U.S.C. 102(e1) as being anticipated by US 20030203447 for the same reasons set forth in the previous Office Action mailed 9/11/06.

Applicant's arguments, filed 3/1/07 and 3/12/07, have been fully considered, but have not been found convincing.

Applicant argues that a rejection under 35 U.S.C. § 102(e) requires a patent filed by another before the invention by the Applicant. In the present case the Applicant for the claims, Dr.

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Horwitz, is the inventor in US Publication No. 2003/0203447 and in the present application. Thus, the cited reference is not by another filed in the United States.

However, instant Applicant names two inventors among them is Dr. Horwitz, thus, the '447 publication has different inventive entity (one inventor), is considered by another.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 31-32 and 34-35 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US 20030203447, XOMA, Better et al; OR Ammons et al, each in view of WO 01/07082.

Applicants submit that the invention was not known or used by others in this country, as required by 35 U.S.C. § 102(a) (XOMA, Better et al) nor was the invention described in a patent by another as required by 35 U.S.C. § 102(e) (US 20030203447) nor described in a printed publication or in public use as required by 35 U.S.C. § 102(b) (Ammons) before the invention thereof by the applicant for patent. Moreover, WO 01/07082 does not disclose the method of Claims 31, 32, 34, or 35 that uses antibodies having the recited sequences.

However, based on the totality of the record as detailed above, the evidence of obviousness found in the combined reference teachings with Applicant's argument for nonobviousness. The Examiner concludes that the claimed invention encompassed by instant claims would have been obvious as a matter of law under 35 U.S.C 103(a).

13. No claim is allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 25, 2007



Maher Haddad, Ph.D.
Primary Examiner
Technology Center 1600